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09/853,753	05/14/2001	N. Torben Bech-Hansen	45499.2	6888

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 05/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/853,753

Applicant(s)

BECH-HANSEN, N. TORBEN

Examiner

Olga N. Chernyshev

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 8-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9 is/are allowed.
- 6) ☒ Claim(s) 1-3, 8 and 10-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 July 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### **DETAILED ACTION**

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 22, 2003 has been entered.

#### ***Response to Amendment***

2. Claims 1 and 9 have been amended and claims 4-7 and 15-24 have been cancelled as requested in the amendment of Paper No. 20, filed on April 22, 2003. Claims 1-3 and 8-14 are pending in the instant application.

Claims 1-3 and 8-14 are under examination in the instant office action.

3. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed on April 22, 2003 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

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***Priority***

6. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file, Paper No. 21.

***Specification***

7. The instant specification is objected to for those reasons of record in section 5 of Paper No. 12. Applicant is advised to carefully review the entire text of the instant specification for proper use of trademarks.

8. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, see page 16, for example. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

9. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825. Specifically, no sequence listing has been provided which includes the sequences presented in Figures 3B and 3D of the instant specification. In case these sequences are new, Applicant needs to provide a substitute computer readable form (CRF) copy of a "Sequence Listing" which includes all of the sequences that are present in the instant application and encompassed by these rules, a substitute paper copy of that "Sequence Listing", an amendment directing the entry of that paper copy into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. §§ 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). The

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instant specification will also need to be amended so that it complies with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. For rules interpretation Applicant may call (703) 308-1123. See M.P.E.P. 2422.04.

### ***Claim Objections***

10. Claims 11 and 13 are objected to because of the following informalities: claims 11 and 13 depend from the cancelled claims. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

11. Claims 1-3, 8 and 11-14, as amended, stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record as applied to claims 1-7 and 9-14 in section 7 of Paper No. 12 and also for reasons of record in section 5 of Paper No. 12.

Applicant submits that "the specification supports the inclusion of an amino acid sequence which is 50% homologous to SEQ ID NO: 2 and further supports the inclusion of conservative amino acid substitutions" (see page 4, third paragraph of Response). These arguments have not been found to be sufficient to overcome written description requirements of 35 U.S.C. 112, first paragraph.

The invention is drawn to a genus of DNA molecules, while the instant specification only describes a nucleic acid molecule of SEQ ID NO:1, which encodes a protein which has the amino acid sequence of SEQ ID NO:2 and fails to teach or describe any other DNA which lacks the nucleic acid sequence of SEQ ID NO:1 and encodes a protein which has functional characteristics of a polypeptide of SEQ ID NO:2. As stated on page 3, third paragraph of Paper No. 14, “[n]yctalopin has not yet been functionally characterized, except that various mutations of NYX are associated with the complete CSNB phenotype”. Thus, because biological significance of the NYX gene was unknown at the time of filing, the instant specification clearly does not provide written description of the whole genus of the claimed DNA because it does not define the complete structure of those molecular embodiments that have functional characteristics of NYX gene. Therefore, there is a lack of guidance or teaching regarding structure and function because there is only a single example provided in the specification and because there is no guidance found in the prior art. Thus, it is concluded that the claims are directed subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

12. Claims 1-3, 8 and 11-14 also stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the DNA molecule having the nucleotide sequence of SEQ ID NO:1, does not reasonably provide enablement for any other DNA molecules for reasons of record as applied to claims 1-7 and 9-14 in section 8 of Paper No. 12. Specifically, based on Applicant’s own statement that function of NYX gene is unknown (page 3, third paragraph of Paper No. 14), one skilled in the art would clearly not be able to use any other

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molecular embodiments specifically recited in claims 1-3 and 9-14 because the only DNA fully disclosed how to use in the instant specification, as filed, is the DNA molecule of SEQ ID NO: 1.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 10-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
14. Claim 10 is vague and indefinite for recitation of "synthetic nucleic acids". As far as it is known all DNA molecules are "synthetic". Clarification is required.
15. Claim 13 recites the limitation "DNA sequence" in claims 1 to 10. There is insufficient antecedent basis for this limitation in the claim.
16. Claim 14 is vague and indefinite in so far as it employs the term "mammalian GPI-anchored small leucine-rich proteoglycan" as a limitation. Without a reference to a precise amino acid sequence identified by a proper SEQ ID NO: one cannot determine the metes and bounds of "mammalian GPI-anchored small leucine-rich proteoglycan". Moreover, because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of a "mammalian GPI-anchored small leucine-rich proteoglycan", an artisan cannot determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation.
17. Claims 11 and 12 are indefinite for being dependent from indefinite claims.

***Conclusion***

18. Claim 9 is allowed. Claims 1-3, 8 and 10-14 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.



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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.  
May 28, 2003

A handwritten signature in cursive script, appearing to read "Olga N. Chernyshev", written in black ink.